

What Is Claimed Is:

1. A pharmaceutical composition comprising Eudragit RL 100 or RS 100 present in an amount of about 10 to about 80% w/w; at least one dissolution modifying excipient, present in a total amount of about 20% to about 70% w/w; a lubricant present in an amount of about 5% to about 25% w/w; and optionally a surfactant present in an amount of 0 to about 10%, a plasticizer present in an amount of 0 to about 10% w/w and/or a processing agent present in an amount of 0 to about 10% w/w.
- 10 2. The composition according to Claim 1 wherein the Eudragit is RL100.
3. The composition according to Claim 2 wherein the Eudragit is RL100 is present in an amount of about 15 to about 50% w/w.
- 15 4. The composition according to Claim 2 wherein the Eudragit RL100 is present in an amount of about 20 to about 40% w/w.
5. The composition according to Claim 1 wherein the surfactant is present in an amount of less than 2% w/w.
- 20 6. The composition according to Claim 5 wherein the surfactant is sodium dodecyl sulphate or is a block copolymer of ethylene oxide and propylene oxide.
7. The composition according to Claim 1 wherein the lubricant is stearyl alcohol, glycerol monostearate (GMS), talc, magnesium stearate, silicon dioxide, amorphous silicic acid, or fumed silica; and combinations or mixtures thereof.
- 25 8. The composition according to Claim 7 wherein the lubricant is present in an amount of about 10 to 30% w/w.
- 30 9. The composition according to Claim 8 wherein the lubricant is stearyl alcohol.
10. The composition according to Claim 9 wherein the stearyl alcohol is present from about 10 to about 15% w/w.
- 35 11. The composition according to Claim 1 wherein the lubricant is stearyl alcohol.

12. The composition according to Claim 11 wherein the stearyl alcohol is present from about 10 to about 15% w/w.
13. The composition according to Claim 1 wherein the dissolution modifying excipient is a swellable solid.
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14. The composition according to Claim 13 wherein the swellable solid is a cellulosic derivatives of ethyl cellulose, cellulose acetate phthalate; hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, or other hydroxyalkylcellulose derivative, and combinations or mixtures thereof.
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15. The composition according to Claim 13 wherein the swellable solid is at least one of a hydroxypropyl cellulose, or hydroxypropylmethyl cellulose, and a combination or mixture thereof.
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16. The composition according to Claim 1 wherein the dissolution modifying excipient is composed of a blend of hydroxypropyl cellulose polymers, each having a differing molecular weight, present in a total amount of about 30% to about 80% w/w.
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17. The composition according to Claim 1 wherein the blend of hydroxypropyl cellulose polymers is Klucel EF and Klucel JF, or Klucel EF, EJ and GF, or Klucel JF and GF.
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18. The composition according to Claim 1 wherein the dissolution modifying excipient is a non-reducing sugar, a low molecular solute, or a water soluble filler.
19. The composition according to Claim 18 wherein the low molecular weight solutes or sugars are xylitol, mannitol, lactose, starch, or sodium chloride, or combinations or mixtures thereof.
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20. The composition according to Claim 1 wherein the dissolution modifying excipient is a disintegrant.
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21. The composition according to Claim 20 wherein the disintegrant is sodium

starch glycollate, croscarmellose sodium, crospovidone (cross-linked polyvinyl pyrrolidone), copovidone, polyvinyl pyrrolidone; and combinations or mixtures thereof.

5 22. The composition according to Claim 1 wherein the plasticizer is triethyl citrate (TEC), tributyl citrate, acetyl triethyl citrate (ATEC), acetyl tributyl citrate (ATBC), dibutyl phthalate, dibutyl sebacate (DBS), diethyl phthalate, vinyl pyrrolidone glycol triacetate, polyethylene glycol, polyoxyethylene sorbitan monolaurate, propylene glycol, or castor oil; and combinations or mixtures thereof.

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23. The composition according to Claim 1 wherein the processing agent is talc.

24. The composition according to Claim 23 wherein the processing agent is present in an amount of about 1 to about 5 % w/w.

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25. The composition according to Claim 1 which further comprises an absorption enhancer.

20 26. The composition according to Claim 25 wherein the absorption enhancer is chitosan, lecithin, lectin, a sucrose fatty acid ester, Vitamin E-TPGS; and combinations or mixtures thereof.

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27. A pharmaceutical composition comprising Eudragit RL100 present in an amount of about 15 to 50% w/w, a lubricant which is stearyl alcohol, and at least one dissolution modifying excipient which is a hydroxypropylcellulose derivative.

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28. The composition according to Claim 27 wherein the hydroxypropyl cellulose is a blend of hydroxypropyl cellulose's having differing molecular weight.

35 29. The composition according to Claim 28 wherein the blend of hydroxypropyl cellulose is Klucel EF and Klucel JF.

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30. The composition according to Claim 1 or 17 wherein the blend of hydroxypropyl cellulose is Klucel JF and Klucel GF.

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31. The composition according to Claim 1 or 17 wherein the blend of

hydroxypropyl cellulose is Klucel EF and Klucel GF.

32. The composition according to any one of Claims 28 to 32 wherein the blend of hydroxypropyl cellulose is of equal % w/w.

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33. The composition according to any one of Claims 28 to 32 wherein the blend of hydroxypropyl cellulose is about 32% w/w.

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34. The composition according to Claim 27 wherein the HPC is present in an amount of about 50% w/w.

35. The composition according to Claim 27 which further comprises a wicking agent.

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36. The composition according to Claim 35 wherein the wicking agent is lactose.

37. The composition according to Claim 36 wherein the lactose is present in an amount of about 13% w/w.

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38. The pharmaceutical composition for molded capsule shells comprising:

#	Formulations	% w/w
1.	Eudragit RL100	25.00
	Klucel GF	50.00
	Lactose	13.00
	Stearyl alcohol	12.00
2.	Eudragit RL100	35.00
	Klucel EF	40.00
	Lactose	13.00
	Stearyl alcohol	12.00
3.	Eudragit RL100	25.00
	Klucel EF	63.00
	Stearyl alcohol	12.00
4.	Eudragit RL100	25.00
	Klucel EF	31.50
	Klucel JF	31.50
	Stearyl alcohol	12.00
#	Formulations	% w/w
5.	Eudragit RL100	25.00

	Klucel EF Lactose Stearyl alcohol	50.00 13.00 12.00
6.	Eudragit RL100 Klucel EF Stearyl alcohol Titanium dioxide	25.00 61.00 12.00 2.00
7.	Eudragit RL100 Klucel EF Stearyl alcohol Succinic acid	24.00 50.00 12.00 13.00
8.	Eudragit RL100 Klucel EF Lactose Stearyl alcohol SDS	24.00 50.00 13.00 12.00 1.00
9.	Eudragit RL100 Eudragit RS100 Klucel EF Klucel JF Stearyl alcohol	21.60 2.40 32.00 32.00 12.00
10.	Eudragit RL100 Eudragit RS100 Klucel EF Klucel JF Stearyl alcohol	2.40 21.60 32.00 32.00 12.00

39. An injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 38.

5 40. A multicomponent injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 38.

10 41. A welded, or mechanically joined, multicomponent injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 38.

42. A multi-component pharmaceutical dosage form which comprises a plurality of sub-units, each sub-unit being selected from

15 a) a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the capsule compartment, and

b) a solid matrix comprising Eudragit RL100 or RS100 present in an amount of

about 15 to 80% w/w, at least one hydroxypropyl cellulose present in an amount of about 30% to about 70% w/w and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the solid matrix, and in which, at least prior to 5 administration to a patient, the sub-units are welded together or mechanically joined in an assembled dosage form.

43. A multi-component pharmaceutical dosage form according to Claim 42, in which the solid matrix also comprises a lubricant present in an amount of about 10 to 10 about 25% w/w.

44. A dosage form according to Claim 42, in which at least one of the sub-units is a drug substance-containing capsule compartments having a wall with a thickness in the range of about 0.1 – 0.8 mm.

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45. A dosage form according to Claim 42, in which at least one of the sub-units is a substantially immediate release sub-unit.